

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)

PRODUCTS LIABILITY)	MDL No. 16-2740
LITIGATION)	SECTION: "H" (5)
)	
This document relates to:)	
Elizabeth Kahn, 16-17039)	

ORDER AND REASONS

Before the Court are several Motions in Limine: Defendants' Omnibus Motion in Limine (Doc. 12968); Plaintiff's Motion in Limine to Preclude Evidence Regarding Sanofi's Corporate Character and Good Acts (Doc. 12892); Plaintiff's Motion in Limine to Exclude Evidence of Healthcare Costs and Insurance as a Collateral Source (Doc. 12888); Plaintiff's Motion in Limine to Bar Prejudicial Litigation Conduct (Doc. 12896); Plaintiff's Motion in Limine to Preclude Testimony and Argument Regarding Plaintiff's Counsel's Advertisements (Doc. 12897); Plaintiff's Motion in Limine to Preclude Testimony and Evidence Regarding "Stem Cell" Staining (Doc. 12889); Plaintiff's Motion in Limine to Preclude Testimony and Evidence Regarding the Personal Use of Taxotere or Other Cancer Drugs and Personal Experience with Cancer (Doc. 12898); Plaintiff's Motion in Limine to Exclude Testimony That Taxotere Has Been Proven Superior to Taxol (or Any Drug Other Than 5-FU), or That Taxotere Have the Plaintiff the "Best Chance" of Surviving Cancer, or That Taxotere Gave Her the "Best Chance" for Preventing Her Cancer From Returning (Doc. 12899); Plaintiff's Motion in Limine to Preclude Defense Counsel from Commenting on or Discussing Certain Matters in the

Presence of the Jury or Potential Jurors by Plaintiff (Doc. 12893); Plaintiff's Motion in Limine to Exclude Evidence of Unrelated Medical Conditions, Unrelated Familial Medical History, and Unrelated Medication Usage (Doc. 12901); Plaintiff's Motion in Limine to Preclude Testimony Regarding Instances of Permanent Alopecia Among Those Prescribed Taxotere by Sanofi's Experts (Doc. 12900); Plaintiff's Motion in Limine to Prohibit the Use of unreliable Evidence to Support Claims of Alternative Causation and/or Questioning Which Misconstrues the Applicable Burden (Doc. 12909); Plaintiff's Motion in Limine to Preclude Any Comment or Argument that Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy (Doc. 12891); Plaintiff's Motion in Limine to Exclude Improper Arguments or Suggestions Regarding FDA Approval (Doc. 12902); Plaintiff's Motion in Limine to Exclude Testimony and Argument That Taxotere Has Saved Lives (Doc. 12890); Plaintiff's Motion in Limine to Exclude Low Quality Photographs (Doc. 12895); Plaintiff's Motion in Limine to Preclude Unsupported Statements from Counsel in Opening and Closing Statements (Doc. 12903); Plaintiff's Motion in Limine to Include Evidence and Argument Regarding Online Advocacy (Doc. 12907); Plaintiff's Motion in Limine to Preclude Any Comment or Argument Concerning Comparative Fault of Her Treating Physicians and Misuse of Taxotere (Doc. 12905); and Plaintiff's Motion in Limine to Preclude Evidence or Argument Concerning the American Cancer Society Breast Cancer Dictionary (Doc. 12894).

BACKGROUND

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,¹ that Plaintiffs were administered

¹ Docetaxel is the generic version of Taxotere.

for the treatment of breast cancer or other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. The second bellwether trial of Plaintiff Elizabeth Kahn (“Plaintiff”) is set to begin November 8, 2021. Plaintiff brings a claim of failure to warn against Defendant.

LAW AND ANALYSIS

The following chart addresses the arguments set forth in each Motion before the Court:

MIL #	Defendant's Motion in Limine to:	Doc. No.	Ruling
1	Preclude Evidence or Argument Concerning the Purported Moral or Ethical Duties of Pharmaceutical Drug Manufacturers	12968	Granted. Subjective opinions on morality or business ethics are irrelevant and thus inadmissible. However, this ruling does not limit testimony on the standard of care.
2	Preclude Evidence or Argument Concerning Purported Legal Duties and Conclusions	12968	Deferred to trial due to vagueness. Experts may properly testify as to FDA regulations and compliance.
3	Preclude Evidence or Argument Concerning Other Lawsuits, Claims, or Investigations Against Defendants and/or Other Sanofi Entities	12968	Granted in part and denied in part. The Court will allow testimony of other lawsuits, claims, or investigations to the extent they relate to alopecia pre-dating Kahn's treatment.
4	Preclude Evidence or Argument Concerning Complaints and Lawsuits Against Other Manufacturers of Docetaxel	12968	Granted in part. Deferred insofar as it concerns any complaints regarding alopecia that were made to the FDA pre-dating Kahn's treatment.

5	Preclude Evidence or Argument Concerning Adverse Event Reports or Other Complaints Involving Patients Other Than Plaintiff	12968	Deferred. The Court will allow experts to refer to adverse event reports for safety signaling which predate Kahn's treatment. Individual adverse event reports are not admissible to prove causation. However, adverse event reports can be admitted as corroborative evidence of causation.
6	Preclude Evidence or Argument Concerning the Presence, Absence, or Identity of Defendants' Corporate Representative at Trial	12968	Granted. Counsel is cautioned, however, not to "vouch" improperly for Sanofi.
7	Preclude Evidence or Argument Concerning Defendants' Executive and/or Employee Compensation	12968	Conditionally granted. ²
8	Preclude Evidence or Argument Concerning the Cost of Taxotere or Prescription Drug Pricing Generally	12968	Conditionally granted.
9	Preclude Evidence or Argument Concerning Defendants' Corporate Finances or Employment Decisions	12968	Conditionally granted.

² "Conditionally granted" as used throughout this Order and Reasons means the motion is granted on its face, but if the door is opened or if the evidence is used for impeachment purposes, it may be admissible. Counsel are cautioned to seek a conference with the Court before introducing the evidence.

10	Preclude Evidence or Argument Concerning Expert Opinions that Exceed the Scope of Plaintiff's Experts' Rule 26 Expert Disclosures	12968	Denied. This matter has previously been addressed in the Court's Daubert rulings.
11	Preclude Evidence or Argument Concerning Defendants' Corporate Intent, Motives, or State of Mind	12968	Granted in part and denied in part. The Court will allow factual evidence that may go to show intent, motive, or state of mind. The Court will not allow speculative testimony on Defendant's intent, motive, or state of mind.
12	Preclude Evidence or Argument Concerning Defendants' Corporate Integrity Agreements, Government Investigations or Settlements, or Any Other Alleged "Bad Acts" Unrelated to Taxotere	12968	Conditionally granted.
13	Preclude Evidence or Argument Concerning Specific Litigation Conduct	12968	Granted.
14	Preclude Evidence or Argument Concerning Alleged Fraud on the FDA	12968	Deferred due to vagueness. The Court specifically notes that there are no allegations of fraud.
15	Preclude Reference to PCIA as "Common"	12968	Denied.
16	Preclude Evidence or Argument Concerning what Plaintiff Would Have Done Differently if She Had Been Given Different Risk Information by her Prescribing Oncologist	12698	Deferred.

17	Preclude Evidence or Argument Concerning Sanofi Promotional and/or Marketing Materials Not Possessed or Relied on by Ms. Kahn or Her Prescribing Physician	12968	Conditionally granted.
18	Preclude Evidence or Argument Concerning Non-Expert Causation Testimony	12968	Deferred. The Court specifically notes that it will not allow non-expert testimony on "causation." However, the Court will allow testimony of friends and family members as to personal observations.
19	Preclude Evidence or Arguments Concerning Plaintiff's Motive and/or Mental State	12968	Granted in part and deferred in part due to vagueness. The Court will allow testimony from others as to their observations of Plaintiff from which the factfinder may infer motive or state of mind. Court will not allow speculative testimony on motive or state of mind.
20	Preclude Evidence or Argument Regarding Sanofi Sales Representatives, and to Exclude Sales Representative Witness Testimony	12968	Denied. What Sanofi knew and when is relevant.
21	Preclude Evidence or Argument Concerning Correspondence Between DDMAC and Sanofi	12968	Conditionally granted.

22	Preclude Evidence or Argument Referring to Sanofi as a “French” or “Foreign” Company	12968	Granted in part and denied in part. The Court will allow testimony establishing that Sanofi is a French corporation. The Court will not allow any improper inference or characterization relating to this fact.
23	Preclude Evidence or Argument Concerning FAERS Signal Evaluation	12968	Denied.
24	Preclude Evidence or Argument Regarding Foreign Labeling and Regulatory Actions	12968	Granted in part and denied in part. The Court will allow testimony as to what information Sanofi provided to foreign regulators. The Court will not allow evidence as to Sanofi’s compliance with foreign regulations.
25	Preclude Evidence and Argument that “Ongoing Alopecia” Data Observed in the TAX316 and GEICAM 9805 Clinical Trials Represents Evidence of “Persistent,” “Permanent,” or “Irreversible” Alopecia	12968	Denied.
26	Preclude Evidence or Argument Regarding Shirley Ledlie, any “Taxotears” or Other Third Party Advocacy or Communications Group or Group Members, Facebook Voices Page, and Intouch Solutions	12968	Conditionally granted.

27	Preclude Evidence and Argument Regarding Company Conduct That Post-Dates Plaintiff's Chemotherapy Treatment	12968	Granted in part and deferred in part. Any evidence of labeling changes occurring after Plaintiff's treatment constitute subsequent remedial measures as contemplated by Federal Rule of Evidence 407. However, such evidence may be used as impeachment evidence. The parties are cautioned to have a conference with the Court regarding any evidence that post-dates Plaintiff's treatment.
28	Preclude Evidence and Argument Concerning FDA's January 2011 Warning Letter and Corresponding 483 Inspection	12968	Conditionally granted.
29	Preclude Evidence or Argument That Plaintiff's Actinic Keratosis Was Caused by Taxotere or PCIA, or Claiming Damages Therefor	12968	Granted in part and denied in part. First, the Court will not allow Plaintiff to argue to the jury that her actinic keratosis was directly caused by Taxotere. Second, Dr. Tosti's testimony regarding actinic keratosis is limited to the topics clearly covered in her deposition. Third, because Plaintiff did not allege actinic keratosis as an element of her damages, she is precluded from claiming any damages therefor at trial.
30	Preclude Evidence or Argument Concerning the Use of Cold Caps	12968	Granted.

31	Preclude Evidence or Argument Concerning the Canadian Informed Consent	12968	Denied. Testimony is limited, however, to Taxotere's input in the Canadian Informed Consent.
32	Preclude Evidence of Argument Concerning Dr. Kessler or His Role in the U.S. Government's COVID-19 Response Team	12968	Conditionally granted.
33	Preclude Duplicative Expert Testimony	12968	Granted.
34	Preclude Punitive Damages Evidence	12968	Conditionally granted.
35	Preclude Evidence or Argument Regarding Dear Health Care Provider Letter	12968	Denied.

MIL #	Plaintiff's Motion in Limine to:	Doc. No.	Ruling
1	Exclude Evidence Regarding Sanofi's Corporate Character and Good Acts	12892	<p>Granted in part and deferred in part. Character evidence is inadmissible pursuant to Rule 404 of the Federal Rules of Evidence. Specifically, the Court will not allow evidence or argument related to the following:</p> <p>(1) Sanofi's contributions to the development of COVID-19 vaccine candidates and its collaboration with GlaxoSmithKline and/or any other partners in the development, production, or distribution of COVID-19 treatments; (2) past and/or planned charitable activities, including sponsorships, medical education, fellowships, and donations; (3) success stories of other pharmaceuticals and treatments; in particular, any evidence framing of Sanofi's general product line, unrelated to Taxotere, as lifesaving; (4) reference to Sanofi as a "job creator", for example, the number of jobs created by Sanofi's building of new manufacturing facilities; (5) any awards and recognitions, which bear no relation to Sanofi's marketing of Taxotere, such as Sanofi's 100% rating on the Human Rights Campaign's Corporate</p>

			Equality Index or Sanofi's U.S. Commerce Department's United States Patent and Trademark Office-granted Patents for Humanity; (6) the Planet Mobilization program and Sanofi's efforts to minimize the environmental impacts of its business through its environmental sustainability initiatives; and (7) Sanofi's research in genomic medicine and gene therapy, investments in research and development unrelated to Taxotere, and any other science and innovation efforts introduced to cast Sanofi and its product line as "cutting edge".
2	Exclude Evidence of Healthcare Costs and Insurance as a Collateral Source	12888	Granted in part and denied in part. The Court will not allow evidence of collateral source payments for medical expenses to be presented to the jury. Nevertheless, the Court will allow Defendant to present to the jury evidence of medical bills paid by Plaintiff's attorney that were incurred by Plaintiff pursuant to this litigation such as the costs associated with her visit with Dr. Tosti and the pathology review conducted by Dr. Thompson.
3	Bar Prejudicial Litigation Conduct	12896	Deferred.

4	Exclude Testimony and Argument Regarding Plaintiff's Counsel's Advertisements	12897	Granted in part and denied in part. The Court will allow such testimony as it relates to Plaintiff, Elizabeth Kahn.
5	Preclude Testimony and Evidence Regarding "Stem Cell" Staining	12889	Granted in part and denied in part. Sanofi may not refer to stem cell staining as a "failed study" but otherwise may discuss it.
6	Preclude Testimony and Argument Regarding the Personal Use of Taxotere or Other Cancer Drugs, or Personal Experiences with Cancer	12898	Deferred. Parties should conference with the Court if they wish to introduce such testimony.
7	Exclude Testimony and Argument that Taxotere Has Been Proven Superior to Taxol - or Any Drug Other Than 5-FU - or That Taxotere Gave Plaintiff the "Best Chance" of Surviving Cancer, or That Taxotere Gave Her the "Best Chance" for Preventing Her Cancer From Returning	12899	Granted in part and denied in part. The Court will not allow testimony that Taxotere has a greater efficacy than Taxol. However, testimony and arguments regarding the respective side effects is relevant to the risk-benefit analysis, and thus is admissible.

8	Preclude Defense Counsel From Commenting On or Discussing Certain Matters in the Presence of the Jury or Potential Jurors	12893	Granted in part and denied in part. The parties are precluded from (1) referencing any settlement negotiations; (2) referencing the number of attorneys involved in the litigation; and (3) evoking sympathy due to litigation crisis or pharmaceutical costs. Parties are, however, allowed leeway in cross-examination to elicit bias and argue that testimony is litigation driven.
9	Exclude Evidence of Unrelated Medical Conditions, Unrelated Familial Medical History, and Unrelated Medication Usage	12901	Granted in part, denied in part, and deferred in part. The Court will not allow defendants' experts to offer speculative testimony about medical conditions for which Plaintiff has no diagnosis. Similarly, Defendants cannot offer testimony regarding medication that Plaintiff does not use. If Defendants have a proper foundation for testimony on medical conditions for which Plaintiff has a diagnosis or medications that Plaintiff uses, Defendants may introduce limited testimony of this nature if it is relevant to determining the cause of Plaintiff's alleged hair loss. The Court will allow limited testimony on Plaintiff's family history of cancer as this is relevant to Plaintiff's state of mind. All other issues are deferred until trial.

10	Preclude Testimony and Evidence Regarding Instances of Permanent Alopecia Among Those Prescribed Taxotere by Sanofi's Experts	12900	Granted. Experts must rely on statistical evidence. Anecdotal evidence is only admissible if it is from Plaintiff's prescribing physician, Dr. Kardinal.
11	Prohibit the Use of Unreliable Evidence to Support Claims of Alternative Causation and/or Questioning which Misconstrues the Applicable Burden	12909	Denied. However, Defendant must have a good faith basis to introduce such evidence. Additionally, this has been previously addressed in the Court's Daubert rulings.
12	Preclude Any Comment or Argument That Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy	12891	Granted in part and denied in part. The Court will allow the parties to elicit testimony regarding the purported increased risk of neuropathy or severity of neuropathy associated with Taxol. The Court, however, will not allow speculative testimony regarding whether the severity of the Plaintiff's neuropathy would or would not have increased with Taxol.

13	Exclude Improper Arguments or Suggestions Regarding FDA Approval	12902	<p>Conditionally granted. Further, the Court notes that it will not permit evidence regarding the FDA's rejection of Sanofi's proposal to add alopecia as a "persistent reaction" to the Taxotere label. To permit such evidence would impermissibly lead the jury to believe that Sanofi attempted to amend the "Adverse Events" section of the label when, in fact, the proposal was to add a "Other Persistent Reactions" section to the label which was specifically in reference to the TAX316 study.</p>
14	Exclude Testimony and Argument That Taxotere Has Saved Lives	12890	<p>Granted in part and denied in part. The efficacy of Taxotere and unsubstantiated claims that it saved Plaintiff's life will be treated differently. The Court will allow evidence and argument regarding the efficacy of Taxotere as it is relevant to the risk-benefit analysis and the prescribing physician's treatment recommendation and decision. However, the Court will not allow Defendant to make unsupported claims that Taxotere saved Plaintiff's life. Consistent with this, the Court will not allow Defendant to argue that the jury should reduce the damage award by the value of Plaintiff's life.</p>

15	Exclude Low Quality Photographs	12895	Deferred until such photographs are presented to the Court.
16	Preclude Unsupported Statements From Counsel in Opening and Closing Statements	12903	Granted.
17	Include Evidence and Argument Regarding Online Advocacy	12907	Denied. The potential prejudicial effect of such evidence substantially outweighs its relevance. However, if Defendant opens the door, a conference with the Court should be held.
18	Preclude Any Comment or Argument Concerning the Comparative Fault of her Treating Physician and Misuse of Taxotere	12905	Granted in part and denied in part. The Court maintains its ruling in <i>Earnest</i> —whether Plaintiff's regimen was “off label” or outside the NCCN guidelines, but nonetheless within the standard of care, is admissible. Additionally, parties may explore the prescribing decision. However, the Court will not allow any evidence of medical malpractice.
19	Preclude Evidence or Argument Concerning the American Cancer Society Breast Cancer Dictionary	12894	Deferred. Party seeking to introduce evidence or make such argument must lay the proper foundation.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that:

- Defendants' First Omnibus Motion in Limine (Doc. 12968) is **GRANTED IN PART, DENIED IN PART, and DEFERRED IN PART**, as set forth herein;
- Plaintiff's Motion in Limine to Exclude Evidence Regarding Sanofi's Corporate Character and Good Acts (Doc. 12892) is **GRANTED IN PART and DEFERRED IN PART**;
- Plaintiff's Motion in Limine to Exclude Evidence of Healthcare Costs and Insurance as a Collateral Source (Doc. 12888) is **GRANTED IN PART** and **DENIED IN PART**;
- Plaintiff's Motion in Limine to Bar Prejudicial Litigation Conduct (Doc. 12896) is **DEFERRED**;
- Plaintiff's Motion in Limine to Exclude Testimony and Argument Regarding Plaintiff's Counsel's Advertisements (Doc. 12897) is **GRANTED IN PART and DENIED IN PART**;
- Plaintiff's Motion in Limine to Preclude Testimony and Evidence Regarding "Stem Cell" Staining (Doc. 12889) is **GRANTED IN PART** and **DENIED IN PART**;
- Plaintiff's Motion in Limine to Preclude Testimony and Argument Regarding the Personal Use of Taxotere or Other Cancer Drugs, or Personal Experiences with Cancer (Doc. 12898) is **DEFERRED**;
- Plaintiff's Motion in Limine to Exclude Testimony and Argument that Taxotere Has Been Proven Superior to Taxol - or Any Drug Other Than 5-FU - or That Taxotere Gave Plaintiff the "Best Chance" of Surviving Cancer, or That Taxotere Gave Her the "Best Chance" for Preventing

Her Cancer From Returning (Doc. 12899) is **GRANTED IN PART** and **DENIED IN PART**;

- Plaintiff's Motion in Limine to Preclude Defense Counsel From Commenting On or Discussing Certain Matters in the Presence of the Jury or Potential Jurors (Doc. 12893) is **GRANTED IN PART** and **DENIED IN PART**;
- Plaintiff's Motion in Limine to Exclude Evidence of Unrelated Medical Conditions, Unrelated Familial Medical History, and Unrelated Medication Usage (Doc. 12901) is **GRANTED IN PART**, **DENIED IN PART**, and **DEFERRED IN PART**;
- Plaintiff's Motion in Limine to Preclude Testimony and Evidence Regarding Instances of Permanent Alopecia Among Those Prescribed Taxotere by Sanofi's Experts (Doc. 12900) is **GRANTED**;
- Plaintiff's Motion in Limine to Prohibit the Use of Unreliable Evidence to Support Claims of Alternative Causation and/or Questioning which Misconstrues the Applicable Burden (Doc. 12909) is **DENIED**;
- Plaintiff's Motion in Limine to Preclude Any Comment or Argument That Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy (Doc. 12891) is **GRANTED IN PART** and **DENIED IN PART**;
- Plaintiff's Motion in Limine to Exclude Improper Arguments or Suggestions Regarding FDA Approval (Doc. 12902) is **CONDITIONALLY GRANTED**;
- Plaintiff's Motion in Limine to Exclude Testimony and Argument That Taxotere Has Saved Lives (Doc. 12890) is **GRANTED IN PART** and **DENIED IN PART**;
- Plaintiff's Motion in Limine to Exclude Low Quality Photographs (Doc. 12895) is **DEFERRED**;

- Plaintiff's Motion in Limine to Preclude Unsupported Statements From Counsel in Opening and Closing Statements (Doc. 12903) is **GRANTED**;
- Plaintiff's Motion in Limine to Include Evidence and Argument Regarding Online Advocacy (Doc. 12907) is **DENIED**;
- Plaintiff's Motion in Limine to Preclude Any Comment or Argument Concerning the Comparative Fault of her Treating Physician and Misuse of Taxotere (Doc. 12905) is **GRANTED IN PART** and **DENIED IN PART**;
- Plaintiff's Motion in Limine to Preclude Evidence or Argument Concerning the American Cancer Society Breast Cancer Dictionary (Doc. 12894) is **DEFERRED**.

New Orleans, Louisiana this 10th day of September, 2021.



JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE